

REMARKS

This Amendment, filed in reply to the Office Action dated December 5, 2008, is believed to be fully responsive to each point of rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Status of Claims and Amendment

Claims 28, 29, 34, 36, and 53-55 are pending in the application. Claims 28-32, 34, 36, 37 and 53 are rejected. Claims 28, 29 and 34 are amended herewith. Claims 30-32 and 37 are canceled. Claims 54 and 55 are added.

Claim 28 is amended to recite “adult tissue-specific cells in order to make the term consistent with the term recited in Claim 29. Support for the amendment can be found throughout the specification, for example, at page 9, lines 31-38.

Claim 29 is amended to correct a typographical error and to recite “in the absence of supporting cells” in order to clarify that the biological matrix or supporting structure recited in Claim 29 are not pre-colonized with supporting cells. Support for the amendment can be found throughout the specification, for example, at page 8, lines 29-38, at page 9, lines 1-18, and original Claims 1-8.

Claims 34 and 36 are amended to recite “the supporting structure” in place of “a supporting structure”

Claims 54 and 55 are added to further define the method of Claim 29, i.e., coating of the matrix or the supporting structure recited in Claim 29 with biodegradable bio-polymers. Support

for the amendment can be found, for example, at page 13, lines 32-36, and at page 14, lines 21-25.

No new matter is added.

Entry of this Amendment is respectfully requested.

Claim Rejections Under 35 U.S.C. § 102

Claims 28-30, 32, 34 and 36-37 remain rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Naughton et al. (“Naughton”, US Patent No. 4,963,489) for the reasons of record.

With regard to Applicant’s assertion that inherent anticipation requires that the reference actually perform the claimed method, the Office Action asserts that it is not required that Naughton specifically exemplify all of the teachings or recognize the specific action of EPO, since the reference teaches culturing the same cells in the presence of EPO as claimed. Thus, the Office Action contends that the claimed subject matter of the present invention is anticipated by Naughton.

In response, solely to advance prosecution of the present application and without acquiescing in the rejection, Claim 29 is amended herewith to recite that the growth of said cells is locally initiated, terminated, and structurally guided in the absence of supporting cells. Subsequently, Claims 32 and 37 are canceled.

Applicant respectfully points out that Naughton does not anticipate the presently claimed invention, which utilizes EPO to achieve three-dimensional growth of adult tissue-specific cells in the absence of supporting cells, because Naughton’s method depends on supporting cells (e.g.,

stromal cells) that are grown sub-confluently in a three-dimensional matrix to provide structural support, growth factors, and regulatory factors for the growth of inoculated cells.

In addition, it is noted that although EPO has been known as a hematopoietic growth factor, the unique property of EPO in promoting structural growth of adult tissue-specific cells, which is distinct from other common growth factors, e.g., HGH or GM-CSF, was unknown until it was discovered by the present invention.

Applicant respectfully points out that the use of EPO in culturing cells is mentioned in Naughton only in the context of optional assistance for obtaining the desired result and thus Naughton does not teach or suggest the non-hematopoietic effect of EPO described in the present invention, i.e., promotion of structural growth of adult tissue-specific cells in culture in the absence of supporting cells.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claims 28-32, 34, 36-37 and 53 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable in view of Naughton et al. (“Naughton”, US 4,963,489) and Chen et al. (“Chen”, US 5076492) for the reasons of record.

Briefly, the Office Action asserts that Naughton teaches the use of growth factors in culturing tissue-specific cells in a three-dimensional (3D) matrix and Chen teaches culturing endothelial cells in the presence of VEGF.

Thus, the Office Action asserts that one of ordinary skill in the art, at the time of the invention, would have been motivated by routine practice and Chen to use any of the claimed growth factors in the methods of Naughton with a reasonable expectation for successfully generating tissues in vitro.

In response to 102(b) rejection, Claim 29 has been amended to recite that the growth of said cells is locally initiated, terminated, and structurally guided in the absence of supporting cells. Subsequently, Claims 32 and 37 have been canceled.

Therefore, for the reasons set forth in Applicant's arguments above, in response to 102(b) rejection, Applicant respectfully points out that Naughton does not teach or suggest culturing adult tissue-specific cells in a matrix in the absence of supporting cells nor teach or suggest the non-hematopoietic effect of EPO.

Chen is relied upon by the Examiner for the proposition that any growth factor, e.g., VEGF, may be used in the method of Naughton. However, the culture method disclosed in Chen is conventional (two-dimensional) aggregate culture. Thus, VEGF would not induce any shape-creating growth but only stimulate the proliferation of endothelial cells under such conditions.

Further, even if one of ordinary skill in the art were somehow motivated to combine teachings of Naughton and Chen, the combined teachings would not result in the method in the claims as amended, i.e., a method for local initiation, termination, and structural guidance of three-dimensional growth of adult tissue-specific cells under the influence of EPO in the absence of supporting cells.

Reconsideration and withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

Claims 54 and 55

Claim 54 recites that the biological matrix or supporting the structure recited in Claim 29 is coated with a biodegradable (bio-) polymer layer comprising exogenous EPO. Claim 55 recites the types of the degradable polymers recited in Claim 54.

Since Claim 54 is dependent from Claim 29, and Claim 55 further defines and limits the subject matter of Claim 54, Applicant submits that Claims 54 and 55 are allowable.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Yong-Jin Choi
Registration No. 61,915

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

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